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10/798,111

03/10/2004

Dario Norberto R. Carrara

88066-7900

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28765 7590 07/15/2009

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PATENT DEPARTMENT
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EXAMINER

SCHLENTZ, NATHAN W

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

07/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|--------------------------|--|---------------------------------------|--|
| Interview Summary | Application No. 10/798,111 | Applicant(s) CARRARA ET AL. | |
| | Examiner Nathan W. Schlientz | Art Unit 1616 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Nathan W. Schlientz. (3) Teresa Chen.

(2) Allan A. Fanucci. (4) ____.

Date of Interview: 07 July 2009.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: 1 and 60.

Identification of prior art discussed: Carrara et al. (WO 02/11768), Mak et al. (US 6,319,913), Bechgaard et al. (US 5,397,771), Dudley et al. (US 6,503,894), and Labrie (US 5,955,455).

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

| | |
|---|---|
| /John Pak/ Primary Examiner, Art Unit 1616 | /Nathan W Schlientz/ Examiner, Art Unit 1616 |
|---|---|

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Attorneys Fanucci and Chen and examiner Schlientz discussed the merits of the case. It was agreed that an amendment to claims 1, 64 and 66, as discussed below, would overcome the rejection under 35 USC 102(b) as being anticipated by Carrara et al. In particular, amending claims 1 to recite, "when the active agent is testosterone, the testosterone is not used as the only active ingredient or if used as the sole active agent, the testosterone is present in an amount of 1% or less by weight of the formulation", and amending claims 64 and 66 to recite, "testosterone present in an amount of 1% or less by weight of the formulation" would sufficiently overcome the rejection because Carrara et al. disclose in Example 2 a gel comprising 1.25 wt.% testosterone. It was only agreed that the aforementioned amendment would overcome the 102(b) rejection under Carrara et al. Agreement was not reached to withdraw the rejection or any other rejection at this time. The examiner explained that this amendment to the claims would require further search and/or consideration and would therefore require filing an RCE in order to be entered.

Attorneys Fanucci and Chen argued that Mak et al. teach the use of a penetration enhancing system comprising oleic acid, which is excluded from the present claims. Also, Mak et al. teach that while the combination of oleic acid and carbopol 1342 produced very low irritating formulations, the incorporation of OTHER irritation reducing agents can FURTHER decrease irritation (emphasis added). Applicants argued that this teaching suggests additional irritation reducing agents as opposed to replacing oleic acid and carbopol with a different irritation reducing agent. However, the examiner respectfully argued that Mak et al. teach one of ordinary skill in the art that oleic acid produces very low irritating formulations, but further irritation can be achieved, and may be desirable. Therefore, one of ordinary skill in the art would be motivated to look to the art to find penetration enhancing systems that result in very low irritation. Thus, the teaching of Bechgaard et al. that n-glycofurol enhance uptake of biologically active substances (i.e., hormones) through a mucosal membrane which acts just as quickly as intravenous injection and results in no irritation for the majority of patients tested was relied upon. Accordingly, it would have been obvious to substitute n-glycofurol, which is a known penetration enhancer that results in no irritation, in the place of oleic acid, which is a known penetration enhancer that results in reduced irritation.

Applicants then discussed amending claim 1 to limit the penetration enhancer to monoalkyl ether of diethylene ether (Transcutol). The examiner then discussed that the teaching of Dudley et al. would have to be taken into consideration that diethylene glycol monoethyl ether is a suitable penetration enhancer for treating hypogonadism with a steroid. Applicants argue that Dudley et al. teach the preferred penetration enhancer is isopropyl myristate, and Transcutol is only mentioned in a long list. Thus, Applicants argue that there is no motivation to choose Transcutol, and then to replace the oleic acid in Mak et al. with Transcutol in Dudley et al. However, the examiner respectfully argued that based on the teaching of Mak et al., one of ordinary skill in the art would be motivated to use a different penetration enhancer that does not result in irritation, and Dudley et al. teach Transcutol as a known penetration enhancer.

Applicants will file a response to the Final office action mailed 5 June 2009, at which point the examiner will consider the arguments and/or amendments.